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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,520	12/04/2000	Ana Rodriguez	GC647	4557

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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

EPPERSON, JON D -

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/21/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*File Copy*

Application No.

09/729,520

Applicant(s)

RODRIGUEZ ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on January 16, 2003 (Paper No. 11).

Priority Claims

2. No foreign or domestic priority is claimed. Therefore, the effective filing date of the claims is the filing date of the case i.e., December 4, 2000.

Status of the Claims

3. Claims 1-7 were pending in the application. In response to the Restriction Requirement, applicants cancelled claim 7 (see Paper No. 11). Therefore, claims 1-6 are currently pending.
4. Applicant's response to the Restriction and/or Election of Species requirements in Paper No. 11 is acknowledged (Applicants elected, Group I, claims 1 (in part), 2-3, 4 (in part) and 5-6 with traverse) and Group II i.e., claims 1 (in part) and 4 (in part) (Please Note: that claim 7, which was also part of Group II, was cancelled by applicants and, consequently, cannot be withdrawn) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being

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drawn to nonelected inventions, there being no allowable generic or linking claim (see below i.e., *Response to Restriction and/or Election of Species*).

5. Therefore, claims 1-6 are examined on the merits in this action. Please note that claims 1-6 are only examined to the extent of the elected species and/or subject matter (see MPEP § 803.02).

Response to Restriction and/or Election of Species

6. Applicant's election of Group I (i.e., claims 1 (in part), 2-3, 4 (in part) and 5-6) in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

7. Applicant's election of species in Paper No. 11 is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has also been treated as an election without traverse (MPEP § 818.03(a)).

8. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

9. The information disclosure statement filed February 7, 2001 (Paper No. 2), fails, in part, to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because two publications cited therein, Quikchange and Tu et al, lack publication dates, a necessary element for consideration. While the other patent and other publications cited therein, and supplied, therewith, have been considered as to the merits, these two publications have not. Applicant is advised that the date of any re-submission of these citations contained in this information disclosure statement or the submission of the missing element – their publication dates – will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

Specification

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bauer et al (US Patent No. 5,932,419) (Date of Patent is **August 3, 1999**).

For *claim 1*, Bauer et al discloses a method for introducing site-directed mutations into circular DNA molecules of interest by means of mutagenic primer pairs (see Bauer et al, entire document, especially abstract), which anticipates claim 1. For example, Bauer et al discloses using a double stranded circular DNA template (see Bauer et al, column 2, lines 42-45; see also column 6, line 36 showing that single stranded DNA may also be used as templates), which anticipates "obtaining a template nucleic acid" in claims 1(a). Furthermore, Bauer et al discloses the use of mutagenic primer "pairs" that contain at least one mutation site with respect to the target sequence (see Bauer et al, column 2, lines 44-46; see also column 4 lines 37-47; see also column 6, last paragraph), which anticipates claim 1 (b) and (c). Bauer et al discloses hybridizing said mutagenic primer pairs to the target sequence (see Bauer et al, column 2, lines 51-52), which anticipates claim 1 (d). Furthermore, Bauer et al discloses the production of more than one mutant strand (i.e., a library of mutant template nucleic acids) via linear cyclic amplification reactions (see Bauer et al, column 2, last paragraph; see especially line 56 and lines 61-62; see also column 7, last paragraph and column 8), which anticipates claim 1 (e).

For *claim 2*, Bauer et al discloses the use of mutagenic primer pairs that are annealed to "opposite" strands of a circular DNA double stranded template i.e., they are separate primers (see Bauer et al, column 2, lines 51-52).

For *claim 3*, Bauer et al discloses first and second oligonucleotides at a concentration of 100 ng/ul (see Bauer et al, column 12, lines 47 and 49), which anticipates claim 3 because 100 ng/ul is less than saturation concentration.

For *claim 4*, Bauer et al discloses that the transformants may contain non-mutanized parent strands that are eventually digested AFTER several cycles of linear cyclic amplification (see Bauer et al, column 9, paragraph 1).

For *claims 5-6*, Bauer et al discloses a template strand that corresponds to the lacZ protein product i.e., β -galactosidase enzyme (see Bauer et al, column 12, "EXAMPLES").

Contact Information

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
April 17, 2003

BENNETT CELSA
PRIMARY EXAMINER

